

REMARKS

Claims 26-35, 41-44 and 46 are pending in the application. Claims 26-35, 41-44 and 46 are rejected. The Office Action Summary mailed on February 11, 2004 indicated a shortened statutory period for response of one (1) month from the mailing of this non-final action. Following a telephonic interview with the Examiner that took place on March 8, 2004, the Examiner provided an Interview Summary, mailed on March 10, 2004, correcting the period for response to a shortened statutory period of three (3) months. Accordingly, this response, along with the accompanying petition for a three month extension of time, is timely filed.

Claim Rejections – 35 U.S.C. §112

Claims 26-35, 41-44 and 46 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that Claim 26 is confusing because the preamble says that the composition is monovalent, but the claim also recites "no more than 15 ug per combined dose of vaccine". Applicants state that the phrase "combined dose" refers not to the valency of the vaccine (i.e., the number of strains represented) but to the number of doses of a monovalent vaccine. The Examiner's attention is respectfully directed to page 6, lines 1-16 wherein it is clear that Applicants' reference to a "combined dose" refers to embodiments of the instant invention wherein the monovalent vaccine is administered in more than one dose, and preferably simultaneously by two different immunization routes. Thus, "monovalent vaccine" and "combined dose" are separate and independent limitations in the claim. Accordingly, Claim 26 and claims dependent thereon are not indefinite.

Claims 26 and 41 stand rejected under 35 U.S.C. §112, second paragraph for recitation of the phrase "a suitable adjuvant". Applicants have amended the claims to specify that the suitable adjuvant is an aluminum salt or salts.

Claims 26-35, 41-44 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner states that Claim 26 pertains to a genus of influenza virus antigens from pandemic or potentially pandemic strains, and that the instant specification provides insufficient guidance to reasonably convey that the Applicants had possession of the genus of pandemic virus antigen. Applicants

traverse and respectfully state that the instant specification and the knowledge of those skilled in this art provide all that is needed to ensure that the inventors had possession of the claimed invention. As pointed out by the Examiner, the specification at page 2, lines 9-25 teaches the characteristics by which one skilled in this art can identify a pandemic strain of influenza virus or a strain with pandemic potential. Moreover, the World Health Organization has published a document entitled an "Influenza Pandemic Plan" published in April of 1999, which can be found at

http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_EDC_99_1/en/, wherein a clear and concise plan for identifying and dealing with a pandemic situation is set forth. Applicants direct the Examiner's attention to page 14 of this document (attached herewith as Exhibit A for the convenience of the Examiner), wherein it is clear that the WHO evaluates and declares when a pandemic condition exists and the identity of the causative viral strain. One skilled in this art, armed with the instant specification (that teaches how to make and use a vaccine against a pandemic influenza strain) and the knowledge in the art (the information provided by the WHO regarding the identity of the causative agent of a pandemic), will be able to practice the instant invention. Accordingly, the specification and the knowledge of the art reasonably conveys to one skilled in this art that Applicants are in full possession of the claimed invention.

Applicants also wish to point out that, contrary to the Examiner's statement, the instant specification does include a working example involving a vaccine against a pandemic strain. Please see Example 5 at pages 24-25 wherein Applicants demonstrate immunogenicity of a vaccine against Influenza virus A/Singapore/1/57, an H2N2 strain associated with the pandemic of 1957 (see Wood, J.M. (2001) Phil. Trans. R. Soc. Lond B 356:1953-1960; copy attached as Exhibit B). Thus, in view of the instant specification, including the working example found therein, and the knowledge in the art, there is no reason for one skilled in this art to doubt that the inventors were in possession of the claimed invention.

Claims 26, 27, 32-35, 41-44 and 46 are also rejected under the written description requirement for recitation of the term "suitable adjuvant". Applicants respectfully assert that in view of the amendments to Claim 26 specifying that suitable adjuvants are aluminum salts, this rejection is now moot.

Prior Art Rejections

Claims 26, 32, 33, 34, 41, 42, 44 and 46 are rejected under 35 U.S.C. 102(a) as being anticipated by Rimmelzwaan et al. Claims 26, 27, 32, 33, 34, 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Couch et al. (J. Infect. Dis., 176:S38-S44, 1997), Chaloupka et al. (Eur. J. Clin. Microbiol. & Infect. Dis., 15: 121-127, 1996), and De Donato et al. (Vaccine, 17: 3094-3131, 1999). Claims 44 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Couch, Chaloupka, and De Donato as applied to claims 26, 27, 32, 33, 34, 41-43 above, and further in view of Riberdy et al. (J. Virol., 73: 1453-1459, 1999).

Applicants traverse and state that the Examiner has acknowledged that claims limited to aluminum salts as adjuvants are free of the prior art (see O.A. at page 7: "Claims 28-31 are free of the prior art, because the prior art generally teaches away from using aluminum salt adjuvants in influenza vaccines."). In view of the amendments to the claims, and particularly the amendments to Claims 26 and 41 wherein the adjuvant is limited to an aluminum salt or salts, all of the pending the claims are now free of the cited prior art.

References To Be Made Of Record

Applicants submit herewith the two references cited in the accompanying supplemental information disclosure statement which have recently come to the Applicants attention. Both references disclose the testing of certain influenza vaccines that utilize δ -aluminum oxide as an adjuvant. The Schenk et al. reference discloses a monovalent influenza vaccine and demonstrates its immunogenicity compared to a non-adjuvanted, "fluid" vaccine. This reference reports the concentration of influenza antigen in International Units (IU) as determined by HA assay, but does not equate IU with an absolute weight of antigen. Thus it is not possible to determine whether the concentration of antigen in this vaccine is within the scope of the instant claims. The Pressler reference does relate IU to micrograms of HA, but does not provide the methodology or algorithm used to convert IU (presumably as determined in the HA assay discussed in Schenk) to micrograms of HA. Moreover, Pressler's vaccine is bivalent, and neither Schenk nor Pressler suggest that the disclosed vaccines are appropriate for use during a pandemic outbreak. Finally, these references were published in 1982, and later references such as Couch et al. raise doubts as to the utility of, and in fact teach away from using, aluminum salt adjuvants in influenza vaccines. Accordingly, even in

view of the Schenk and Pressler references, one skilled in the art lacks any guidance to prepare a vaccine as claimed in the instant claims.

In view of the foregoing amendments and remarks, Applicants respectfully submit that the subject application is in condition for allowance. If the Examiner has any remaining objections or concerns, the Examiner is respectfully requested to contact Applicants' undersigned attorney to resolve such issues and advance the case to issue.

Respectfully submitted,



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